

1           AMY W. SCHULMAN  
2           DLA PIPER LLP  
3           1251 Avenue of the Americas  
4           New York, NY 10020  
3           Telephone: (212) 335-4500  
4           Facsimile: (212) 335-4501  
4           amy.schulman@dlapiper.com

5 STUART M. GORDON (SBN: 037477)  
6 GORDON & REES LLP  
7 Embarcadero Center West  
8 275 Battery Street, Suite 2000  
9 San Francisco, CA 94111  
10 Telephone: (415) 986-5900  
11 Facsimile: (415) 986-8054  
12 sgordon@gordonrees.com

0 MICHAEL C. ZELLERS (SBN: 146904)  
1 TUCKER ELLIS & WEST LLP  
2 515 South Flower Street, Suite 4200  
3 Los Angeles, CA 90071-2223  
4 Telephone: (213) 430-3400  
5 Facsimile: (213) 430-3409  
6 michael.zellers@tuckerellis.com

4 Attorneys for Defendants  
- PFIZER INC., PHARMACIA CORPORATION, AND  
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION ) MDL Docket No. 1699  
This document relates to )  
WILLIAM POTEATE, ) CASE NO. 3:07-cv-4794-CRB  
Plaintiff, )  
vs. )  
PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE & CO., )  
Defendants )  
PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE, LLC'S ANSWER TO COMPLAINT  
JURY DEMAND ENDORSED HEREIN

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiff's Complaint as "G.D. Searle LLC") ("Searle") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

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## **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used  
9 Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally.  
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time  
11 periods in which Plaintiff was prescribed and used Bextra®.

II.

## ANSWER

## **Response to Allegations Regarding Parties**

15. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but  
16. deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain  
17. periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States  
18. to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19. accordance with their approval by the FDA. Defendants admit that, during certain periods of  
20. time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,  
21. co-promoted and distributed Bextra® in the United States to be prescribed by healthcare  
22. providers who are by law authorized to prescribe drugs in accordance with their approval by the  
23. FDA. Defendants state that Bextra® was and is safe and effective when used in accordance  
24. with its FDA-approved prescribing information. Defendants state that the potential effects of  
25. Bextra® were and are adequately described in its FDA-approved prescribing information,  
26. which was at all times adequate and comported with applicable standards of care and law.  
27. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,  
28. and deny the remaining allegations in this paragraph of the Complaint.

1 2. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.  
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 3. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
5 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
6 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
7 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted  
8 Bextra® in the United States, including North Carolina, to be prescribed by healthcare  
9 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
10 FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are  
11 vague and ambiguous. Defendants are without knowledge or information to form a belief as to  
12 the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining  
13 allegations in this paragraph of the Complaint.

14 4. Defendants admit that Searle is a Delaware limited liability company with its principal  
15 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®  
16 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted  
17 and distributed Bextra® in the United States to be prescribed by healthcare providers who are  
18 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
19 deny the remaining allegations in this paragraph of the Complaint.

20 5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
21 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia  
22 marketed and co-promoted Bextra® in the United States, including North Carolina, to be  
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
24 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding  
25 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
26 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
27 Defendants deny the remaining allegations in this Paragraph of the Complaint.

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## **Response to Allegations Regarding Jurisdiction and Venue**

6. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

8. Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing , Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the State of North Carolina or the State of California and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States, North Carolina, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit that they do business in the State of North Carolina. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without

1 knowledge or information to form a belief as to the truth of such allegations, and, therefore,  
2 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in  
3 this paragraph of the Complaint.

4 **Response to Allegations Regarding Interdistrict Assignment**

5 10. Defendants state that this paragraph of the Complaint contains legal contentions to  
6 which no response is required. To the extent that a response is deemed required, Defendants  
7 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
8 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
9 Panel on Multidistrict Litigation on September 6, 2005.

10 **Response to Factual Allegations**

11 11. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
13 Defendants deny the remaining allegations this paragraph of the Complaint.

14 12. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
16 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
17 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph  
18 of the Complaint.

19 13. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
21 Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Bextra® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
26 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph  
27 of the Complaint.

28 14. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
2 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
3 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph  
4 of the Complaint.

5 15. Defendants admit that Bextra® was expected to reach consumers without substantial  
6 change from the time of sale. Defendants are without knowledge or information sufficient to  
7 form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,  
8 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the  
9 Complaint.

10 16. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
15 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
16 Defendants deny remaining the allegations in this paragraph of the Complaint.

17 17. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-  
18 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe  
19 and effective when used in accordance with its FDA-approved prescribing information.  
20 Defendants state that the potential effects of Bextra® were and are adequately described in its  
21 FDA-approved prescribing information, which was at all times adequate and comported with  
22 applicable standards of care and law. Defendants deny the remaining allegations in this  
23 paragraph of the Complaint.

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1 18. The allegations in this paragraph of the Complaint are not directed toward Defendants  
2 and, therefore, no response is required. To the extent a response is deemed required,  
3 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
4 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
5 form a belief as to the truth of such allegations and, therefore, deny the same.

6 19. The allegations in this paragraph of the Complaint are not directed toward Defendants  
7 and, therefore, no response is required. To the extent a response is deemed required,  
8 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
9 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
10 form a belief as to the truth of such allegations and, therefore, deny the same.

11 20. Plaintiff fails to provide the proper context for the allegations in this paragraph of the  
12 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth  
13 of such allegations and, therefore, deny the same.

14 21. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are  
15 vague and ambiguous. Defendants are without knowledge or information to form a belief as to  
16 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful  
17 conduct and deny the remaining allegations in this paragraph of the Complaint.

18 22. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,  
19 Defendants admit that Celebrex® was launched in the United States in February 1999.  
20 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
21 FDA-approved prescribing information. Defendants admit that, during certain periods of time,  
22 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
24 with their approval by the FDA. Defendants admit that, during certain periods of time,  
25 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
26 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
27 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
28 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not

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1 directed toward Defendants and, therefore, no response is required. To the extent a response is  
2 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
3 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants  
4 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
5 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this  
6 paragraph of the Complaint.

7 23. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
8 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the  
9 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis  
10 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.  
11 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and  
12 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
13 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in  
14 this paragraph of the Complaint.

15 24. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.  
16 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is  
17 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
18 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining  
19 allegations in this paragraph of the Complaint.

20 25. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
21 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
22 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny  
23 the remaining allegations in this paragraph of the Complaint.

24 26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
25 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
26 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
27 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
28 prescribing information. Defendants state that the potential effects of Bextra® were and are

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1 adequately described in its FDA-approved prescribing information, which at all times was  
2 adequate and comported with applicable standards of care and law. Defendants deny the  
3 remaining allegations in this paragraph of the Complaint.

4 27. Defendants state that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which at all times was adequate and comported with applicable standards of care and law.  
8 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
9 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
11 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
12 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
13 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
14 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding  
15 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
16 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
18 the Complaint.

19 28. Defendants state that the referenced article speaks for itself and respectfully refer the  
20 Court to the article for its actual language and text. Any attempt to characterize the article is  
21 denied. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
23 this paragraph of the Complaint.

24 29. The allegations in this paragraph of the Complaint are not directed towards Defendants  
25 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
26 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
27 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
28 the remaining allegations in this paragraph of the Complaint.

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1 30. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
2 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November  
3 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this  
4 paragraph of the Complaint.

5 31. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which at all times was adequate and comported with applicable standards of care and law.  
9 Defendants deny the allegations in this paragraph of the Complaint.

10 32. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which at all times was adequate and comported with applicable standards of care and law.  
14 Defendants deny the allegations in this paragraph of the Complaint.

15 33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and  
16 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to  
17 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this  
18 paragraph of the Complaint.

19 34. Defendants state that the referenced article speaks for itself and respectfully refer the  
20 Court to the article for its actual language and text. Any attempt to characterize the article is  
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 35. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug  
23 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without  
24 sufficient information to confirm or deny such allegations and, therefore, deny the same.  
25 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
26 the study for its actual language and text. Any attempt to characterize the study is denied.  
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 36. The allegations in this paragraph of the Complaint are not directed towards Defendants

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1 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
2 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk  
3 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the  
4 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its  
5 actual language and text. Any attempt to characterize the testimony is denied. Defendants  
6 deny the remaining allegations in this paragraph of the Complaint.

7 37. Defendants state that Bextra® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
9 deny the remaining allegations in this paragraph of the Complaint.

10 38. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
11 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
12 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
15 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
16 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 40. Defendants state that the referenced article speaks for itself and respectfully refer the  
19 Court to the article for its actual language and text. Any attempt to characterize the article is  
20 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 41. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
23 this paragraph of the Complaint.

24 42. Defendants state that the referenced article speaks for itself and respectfully refer the  
25 Court to the article for its actual language and text. Any attempt to characterize the article is  
26 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 43. Defendants state that the referenced article speaks for itself and respectfully refer the  
28 Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 44. Defendants state that the referenced articles speak for themselves and respectfully refer  
3 the Court to the articles for their actual language and text. Any attempt to characterize the  
4 articles is denied. Defendants deny the remaining allegations in this paragraph of the  
5 Complaint.

6 45. Defendants state that the referenced article speaks for itself and respectfully refer the  
7 Court to the article for its actual language and text. Any attempt to characterize the article is  
8 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 46. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants deny the allegations in this  
11 paragraph of the Complaint.

12 47. Defendants state that the referenced article speaks for itself and respectfully refer the  
13 Court to the article for its actual language and text. Any attempt to characterize the article is  
14 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
15 paragraph of the Complaint.

16 48. The allegations in this paragraph of the Complaint are not directed towards Defendants  
17 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
18 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
19 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
20 the remaining allegations in this paragraph of the Complaint.

21 49. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny the allegations in this paragraph of the Complaint.

26 50. Defendants state that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
3 allegations in this paragraph of the Complaint.

4 51. Defendants state that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
11 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
12 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
13 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
14 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
15 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
16 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 state that the potential effects of Bextra® were and are adequately described in its FDA-  
19 approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants are without knowledge or information  
21 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used  
22 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
23 allegations in this paragraph of the Complaint.

24 53. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed  
25 toward Defendants and, therefore, no response is required. To the extent a response is deemed  
26 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in  
27 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient  
28 information or knowledge to form a belief as to the truth of such allegations and, therefore,

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1 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in  
2 this paragraph of the Complaint.

3 54. Defendants state that the referenced article speaks for itself and respectfully refer the  
4 Court to the article for its actual language and text. Any attempt to characterize the article is  
5 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
6 paragraph of the Complaint.

7 55. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
13 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Bextra® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny the remaining allegations in this  
18 paragraph of the Complaint.

19 56. Defendants state that Bextra® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants state that the potential effects of  
21 Bextra® were and are adequately described in its FDA-approved prescribing information,  
22 which was at all times adequate and comported with applicable standards of care and law.  
23 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and  
24 deny the remaining allegations in this paragraph of the Complaint.

25 57. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
26 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
27 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
28 actual language and text. Any attempt to characterize the letter is denied. Defendants admit

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1 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
2 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual  
3 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
4 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
5 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to  
6 characterize the transcripts is denied. Defendants state that the referenced study speaks for  
7 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
8 to characterize the article is denied. Defendants deny the remaining allegations in this  
9 paragraph of the Complaint.

10 58. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
11 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
12 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
13 that the referenced press release speaks for itself and respectfully refer the Court to the press  
14 release for its actual language and text. Any attempt to characterize the press release is denied.  
15 Defendants state that the referenced article speaks for itself and respectfully refer the Court to  
16 the article for its actual language and text. Any attempt to characterize the article is denied.  
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
18 the Complaint.

19 59. Defendants state that the referenced press release speaks for itself and respectfully refer  
20 the Court to the press release for its actual language and text. Any attempt to characterize the  
21 press release is denied. Defendants deny any wrongful conduct and deny the remaining  
22 allegations in this paragraph of the Complaint.

23 60. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
26 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
2 effective when used in accordance with its FDA-approved prescribing information. Defendants  
3 state that the potential effects of Bextra® were and are adequately described in its FDA-  
4 approved prescribing information, which was at all times adequate and comported with  
5 applicable standards of care and law. Defendants admit, as indicated in the package insert  
6 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms  
7 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary  
8 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 61. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which at all times was adequate and comported with applicable standards of care and law.  
13 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and  
14 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
15 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny  
16 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

17 62. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
18 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
19 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
20 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
21 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
22 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
23 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
24 effective when used in accordance with its FDA-approved prescribing information. Defendants  
25 state that the potential effects of Bextra® were and are adequately described in its FDA-  
26 approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny the remaining allegations in this  
28 paragraph of the Complaint.

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1 63. Defendants state that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Bextra® were and are adequately described in its FDA-approved prescribing information,  
4 which at all times was adequate and comported with applicable standards of care and law.  
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 64. Defendants state that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 65. Defendants state that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 66. Defendants deny the allegations in this paragraph of the Complaint.

19 67. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
20 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
21 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
22 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
23 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
24 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
25 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
26 effective when used in accordance with its FDA-approved prescribing information. Defendants  
27 state that the potential effects of Bextra® were and are adequately described in its FDA-  
28 approved prescribing information, which was at all times adequate and comported with

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 68. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the  
5 same. Defendants state that the referenced press releases speak for themselves and respectfully  
6 refer the Court to the press releases for their actual language and text. Any attempt to  
7 characterize the press releases is denied. Defendants state that Bextra® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 state that the potential effects of Bextra® were and are adequately described in its FDA-  
10 approved prescribing information, which was at all times adequate and comported with  
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
12 remaining allegations in this paragraph of the Complaint.

13 69. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the  
15 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,  
20 and deny the remaining allegations in this paragraph of the Complaint.

21 70. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
26 allegations in this paragraph of the Complaint.

27 71. Defendants state that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 72. Defendants deny any wrongful conduct and deny the remaining allegations in this  
6 paragraph of the Complaint.

7 73. Defendants state that Bextra® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Bextra® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
12 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
14 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
15 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
16 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
17 with their approval by the FDA. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 74. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
20 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
21 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
22 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
23 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
24 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
25 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
26 paragraph of the Complaint.

27 **Response to First Cause of Action: Negligence**

28 75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's

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1 Complaint as if fully set forth herein.

2 76. Defendants state that this paragraph of the Complaint contains legal contentions to  
3 which no response is deemed required. To the extent a response is deemed required,  
4 Defendants admit that they had duties as are imposed by law but deny having breached such  
5 duties. Defendants state that the potential effects of Bextra® were and are adequately described  
6 in its FDA-approved prescribing information, which was at all times adequate and comported  
7 with applicable standards of care and law. Defendants state that Bextra® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 deny the remaining allegations in this paragraph of the Complaint.

10 77. Defendants state that this paragraph of the Complaint contains legal contentions to  
11 which no response is deemed required. To the extent a response is deemed required,  
12 Defendants admit that they had duties as are imposed by law but deny having breached such  
13 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
15 this paragraph of the Complaint.

16 78. Defendants state that this paragraph of the Complaint contains legal contentions to  
17 which no response is required. To the extent that a response is deemed required, Defendants  
18 admit that they had duties as are imposed by law but deny having breached such duties.  
19 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
20 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
21 were and are adequately described in its FDA-approved prescribing information, which was at  
22 all times adequate and comported with applicable standards of care and law. Defendants deny  
23 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,  
24 including all subparts.

25 79. Defendants state that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
2 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 80. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 81. Defendants state that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
13 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
14 paragraph of the Complaint.

15 82. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
20 the Complaint.

21 83. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed  
22 toward Defendants and, therefore, no response is required. To the extent a response is deemed  
23 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in  
24 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient  
25 information or knowledge to form a belief as to the truth of such allegations and, therefore,  
26 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in  
27 this paragraph of the Complaint.

28 84. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
2 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
3 paragraph of the Complaint.

4 85. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 86. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
7 damage and deny the remaining allegations in this paragraph of the Complaint.

8 87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Second Cause of Action: Strict Liability**

11 88. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
12 Complaint as if fully set forth herein.

13 89. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
15 Defendants admit that Bextra® was expected to reach consumers without substantial change in  
16 the condition from the time of sale. Defendants admit that, during certain periods of time,  
17 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed  
18 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
19 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was  
20 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
21 distributed Bextra® in the United States to be prescribed by healthcare providers who are by  
22 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
23 state that Bextra® was and is safe and effective when used in accordance with its FDA-  
24 approved prescribing information. Defendants state that the potential effects of Bextra® were  
25 and are adequately described in its FDA-approved prescribing information, which was at all  
26 times adequate and comported with applicable standards of care and law. Defendants deny the  
27 remaining allegations in this paragraph of the Complaint.

28 90. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
2 Bextra® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants deny the allegations in this paragraph of the Complaint.

5 91. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining  
10 allegations in this paragraph of the Complaint.

11 92. Defendants state that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants state that the potential effects of  
13 Bextra® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.  
15 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining  
16 allegations in this paragraph of the Complaint.

17 93. Defendants state that this paragraph of the Complaint contains legal contentions to  
18 which no response is required. To the extent that a response is deemed required, Defendants  
19 are without knowledge or information sufficient to form a belief as to the truth of the  
20 allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants  
21 state that Bextra® was and is safe and effective when used in accordance with its FDA-  
22 approved prescribing information. Defendants state that the potential effects of Bextra® were  
23 and are adequately described in its FDA-approved prescribing information, which was at all  
24 times adequate and comported with applicable standards of care and law. Defendants deny that  
25 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this  
26 paragraph of the Complaint, including all subparts.

27 94. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

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1 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
2 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
3 were and are adequately described in its FDA-approved prescribing information, which was at  
4 all times adequate and comported with applicable standards of care and law. Defendants deny  
5 that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this  
6 paragraph of the Complaint.

7 95. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
9 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
10 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
11 were and are adequately described in its FDA-approved prescribing information, which was at  
12 all times adequate and comported with applicable standards of care and law. Defendants deny  
13 that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

14 96. Defendants state that this paragraph of the Complaint contains legal contentions to  
15 which no response is deemed required. To the extent a response is deemed required,  
16 Defendants deny the allegations in this paragraph of the Complaint.

17 97. Defendants state that Bextra® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Bextra® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®  
22 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the  
23 Complaint.

24 98. Defendants state that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Bextra® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining

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1 allegations in this paragraph of the Complaint.

2 99. Defendants are without knowledge or information sufficient to form a belief as to the  
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
4 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
5 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
6 were and are adequately described in its FDA-approved prescribing information, which was at  
7 all times adequate and comported with applicable standards of care and law. Defendants admit  
8 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®  
9 in the United States to be prescribed by healthcare providers who are by law authorized to  
10 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during  
11 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,  
12 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by  
13 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
14 approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective,  
15 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
16 paragraph of the Complaint.

17 100. Defendants state that Bextra® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Bextra® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 101. Defendants state that this paragraph of the Complaint contains legal contentions to  
23 which no response is deemed required. To the extent a response is deemed required,  
24 Defendants admit that they had duties as are imposed by law but deny having breached such  
25 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 102. Defendants are without knowledge or information sufficient to form a belief as to the  
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
4 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
5 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
6 were and are adequately described in its FDA-approved prescribing information, which was at  
7 all times adequate and comported with applicable standards of care and law. Defendants deny  
8 the remaining allegations in this paragraph of the Complaint.

9 103. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
11 deny the remaining allegations in this paragraph of the Complaint.

12 104. Defendants state that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 105. Defendants state that Bextra® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
20 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
21 paragraph of the Complaint.

22 106. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 107. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 108. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28

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## **Response to Third Cause of Action: Breach of Express Warranty**

109. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

111. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

112. Defendants deny the allegations in this paragraph of the Complaint.

113. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants admit that they provided FDA-approved prescribing information regarding  
4 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of  
5 the Complaint.

6 115. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
8 Defendants admit that they provided FDA-approved prescribing information regarding  
9 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 116. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint.

16 117. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
18 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
19 paragraph of the Complaint.

20 118. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 119. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 120. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Fourth Cause of Action: Breach of Implied Warranty**

27 121. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
28 Complaint as if fully set forth herein.

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1 122. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
2 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
3 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
4 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
5 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
6 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
7 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
8 paragraph of the Complaint.

9 123. Defendants admit that they provided FDA-approved prescribing information regarding  
10 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that  
11 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
12 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
13 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
14 prescribing information. Defendants deny the remaining allegations in this paragraph of the  
15 Complaint.

16 124. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
18 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is  
19 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
20 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining  
21 allegations in this paragraph of the Complaint.

22 125. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
24 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
25 FDA-approved prescribing information. Defendants deny the remaining allegations in this  
26 paragraph of the Complaint.

27 126. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

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1 Defendants state that Bextra® was expected to reach consumers without substantial change in  
2 the condition from the time of sale. Defendants deny the remaining allegations in this  
3 paragraph of the Complaint.

4 127. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
6 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
7 FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the  
8 remaining allegations in this paragraph of the Complaint.

9 128. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
14 the Complaint.

15 129. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
17 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
18 paragraph of the Complaint.

19 130. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
20 damage, and deny the remaining allegations in this paragraph of the Complaint.

21 131. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 132. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

26 133. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
27 Complaint as if fully set forth herein.

28 134. Defendants state that this paragraph of the Complaint contains legal contentions to

1 which no response is deemed required. To the extent a response is deemed required,  
2 Defendants admit that they had duties as are imposed by law but deny having breached such  
3 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 135. Defendants state that Bextra® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Bextra® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint, including all subparts.

14 136. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 137. Defendants state that Bextra® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Bextra® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably  
25 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

26 138. Defendants state that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
3 the Complaint.

4 139. Defendants deny any wrongful conduct and deny the remaining allegations in this  
5 paragraph of the Complaint.

6 140. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 141. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint.

14 142. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 143. Defendants deny any wrongful conduct and deny the remaining allegations in this  
19 paragraph of the Complaint.

20 144. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
22 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
23 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
24 were and are adequately described in its FDA-approved prescribing information, which was at  
25 all times adequate and comported with applicable standards of care and law. Defendants deny  
26 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 145. Defendants state that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 146. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
7 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 147. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 148. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
12 damage, and deny the remaining allegations in this paragraph of the Complaint.

13 149. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Sixth Cause of Action: Unjust Enrichment**

16 150. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
17 Complaint as if fully set forth herein.

18 151. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
24 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
25 paragraph of the Complaint.

26 152. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

1 153. Defendants are without knowledge or information sufficient to form a belief as to the  
 2 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
 3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 154. Defendants are without knowledge or information sufficient to form a belief as to the  
 5 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
 6 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
 7 FDA-approved prescribing information. Defendants deny the remaining allegations in this  
 8 paragraph of the Complaint.

9 155. Defendants are without knowledge or information sufficient to form a belief as to the  
 10 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.  
 11 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,  
 12 and deny the remaining allegations in this paragraph of the Complaint.

13 156. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or  
 14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Prayer for Relief**

16 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"  
 17 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,  
 18 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

19 **III.**

20 **GENERAL DENIAL**

21 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's  
 22 Complaint that have not been previously admitted, denied, or explained.

23 **IV.**

24 **AFFIRMATIVE DEFENSES**

25 Defendants reserve the right to rely upon any of the following or additional defenses to  
 26 claims asserted by Plaintiff to the extent that such defenses are supported by information  
 27 developed through discovery or evidence at trial. Defendants affirmatively show that:

Gordon & Rees, LLP  
 275 Battery Street, Suite 2000  
 San Francisco, CA 94111

**Gordon & Rees, LLP**  
**275 Battery Street, Suite 2000**  
**San Francisco CA 94111**

## First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

## **Second Defense**

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

### **Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

## **Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

## Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

## **Sixth Defense**

6. Plaintiff's action is barred by the statute of repose.

## **Seventh Defense**

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

**Gordon & Rees, LLP**  
**2275 Battery Street, Suite 2000**  
**San Francisco CA 94111**

## Eighth Defense

2 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or  
3 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the  
4 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not  
5 liable in any way.

## **Ninth Defense**

7 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,  
8 intervening causes for which Defendants cannot be liable.

## **Tenth Defense**

10 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were  
11 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act  
12 of God.

## **Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

## **Twelfth Defense**

16 12. A manufacturer has no duty to warn patients or the general public of any risk,  
17 contraindication, or adverse effect associated with the use of a prescription medical product.  
18 Rather, the law requires that all such warnings and appropriate information be given to the  
19 prescribing physician and the medical profession, which act as a “learned intermediary” in  
20 determining the use of the product. Bextra® is a prescription medical product, available only  
21 on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s  
22 treating and prescribing physicians.

## **Thirteenth Defense**

24 13. The product at issue was not in a defective condition or unreasonably dangerous at the  
25 time it left the control of the manufacturer or seller.

## **Fourteenth Defense**

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

## **Fifteenth Defense**

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

## **Sixteenth Defense**

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

## Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

## **Eighteenth Defense**

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

## Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

## Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

## Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

## **Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

## **Twenty-third Defense**

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

## **Twenty-fourth Defense**

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

## Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

## Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

## **Twenty-seventh Defense**

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

## Twenty-eighth Defense

2 28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
3 Products Liability.

## Twenty-ninth Defense

5 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead  
6 facts sufficient under the law to justify an award of punitive damages.

## **Thirtieth Defense**

8 30. The imposition of punitive damages in this case would violate Defendants' rights to  
9 procedural due process under the Fourteenth Amendment of the United States Constitution, the  
10 Constitution of the State of North Carolina, and the Constitution of the State of California, and  
11 would additionally violate Defendants' right to substantive due process under the Fourteenth  
12 Amendment of the United States Constitution.

## **Thirty-first Defense**

14 31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and  
15 Fourteenth Amendments to the United States Constitution.

## **Thirty-second Defense**

17 32. The imposition of punitive damages in this case would violate the First Amendment to  
18 the United States Constitution.

### **Thirty-third Defense**

20 | 33. Plaintiff's punitive damage claims are preempted by federal law.

## **Thirty-fourth Defense**

22 34. In the event that reliance was placed upon Defendants' nonconformance to an express  
23 representation, this action is barred as there was no reliance upon representations, if any, of  
24 Defendants.

## **Thirty-fifth Defense**

26 35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance  
27 to any express representation.

## **Thirty-sixth Defense**

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

### **Thirty-seventh Defense**

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

## Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of North Carolina and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally

1 sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to  
 2 satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v.*  
 3 *Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S.  
 4 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut.*  
 5 *Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
 8 and marketing of Bextra®, if any, used in this case, included adequate warnings and  
 9 instructions with respect to the product's use in the package insert and other literature, and  
 10 conformed to the generally recognized, reasonably available, and reliable state of the  
 11 knowledge at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,  
 14 manufactured and labeled in accordance with the state-of-the-art industry standards existing at  
 15 the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information  
 18 and belief, such injuries and losses were caused by the actions of persons not having real or  
 19 apparent authority to take said actions on behalf of Defendants and over whom Defendants had  
 20 no control and for whom Defendants may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®  
 23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
 24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,  
 27 waiver, and/or estoppel.

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## **Forty-fourth Defense**

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

## **Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

## **Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

## **Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

## Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

## **Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

## **Fiftieth Defense**

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

## **Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

## **Fifty-second Defense**

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

## **Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff’s claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

## Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

## Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

## Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

## **Fifty-eighth Defense**

58. Upon information and belief, Plaintiff's claims may be barred by the provisions of N.C. Gen. Stat. § 99B-4(1) in that the use of the product may have been contrary to express and adequate instructions or warnings provided to Plaintiff by Plaintiff's physician(s).

## Fifty-ninth Defense

59. Upon information and belief, Plaintiff continued to use Bextra® after learning of its alleged defects. Accordingly, Plaintiff's claims are barred by North Carolina common law and N.C. Gen. Stat. § 99B-4(2).

## **Sixtieth Defense**

60. If it is discovered that Plaintiff failed to exercise reasonable care under the circumstances in the use of Bextra®, and Plaintiff's failure was a proximate cause of Plaintiff's alleged injuries, then the provisions of N.C. Gen. Stat. § 99B-4(3) are pled as a complete bar to Plaintiff's right to recover against Defendants.

## **Sixty-first Defense**

61. Plaintiff's claims are barred by N.C. Gen. Stat. § 99B-5(c), which expressly limits Defendants' responsibility to provide product warnings directly to consumers of prescription drugs.

## Sixty-second Defense

62. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

## **PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

**Gordon & Rees, LLP**  
**2275 Battery Street, Suite 2000**  
**San Francisco, CA 94111**

1 December 12, 2007

GORDON & REES LLP

2 By: \_\_\_\_\_/s/

3 Stuart M. Gordon  
4 sgordon@gordonrees.com  
5 Embarcadero Center West  
6 275 Battery Street, 20<sup>th</sup> Floor  
7 San Francisco, CA 94111  
8 Telephone: (415) 986-5900  
9 Fax: (415) 986-8054

10 December 12, 2007

TUCKER ELLIS & WEST LLP

11 By: \_\_\_\_\_/s/

12 Michael C. Zellers  
13 michael.zellers@tuckerellis.com  
14 515 South Flower Street, Suite 4200  
15 Los Angeles, CA 90071-2223  
16 Telephone: (213) 430-3400  
17 Fax: (213) 430-3409

18 Attorneys for Defendants  
19 PFIZER INC., PHARMACIA  
20 CORPORATION, AND G.D. SEARLE  
21 LLC

22 Gordon & Rees, LLP  
23 275 Battery Street, Suite 2000  
24 San Francisco, CA 94111

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a  
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil  
4 Procedure.

5 December 12, 2007

GORDON & REES LLP

6  
7 By: \_\_\_\_\_/s/  
8 Stuart M. Gordon  
9 sgordon@gordonrees.com  
10 Embarcadero Center West  
11 275 Battery Street, 20<sup>th</sup> Floor  
12 San Francisco, CA 94111  
13 Telephone: (415) 986-5900  
14 Fax: (415) 986-8054

15 December 12, 2007

TUCKER ELLIS & WEST LLP

16 By: \_\_\_\_\_/s/  
17 Michael C. Zellers  
18 michael.zellers@tuckerellis.com  
19 515 South Flower Street, Suite 4200  
20 Los Angeles, CA 90071-2223  
21 Telephone: (213) 430-3400  
22 Fax: (213) 430-3409

23 Attorneys for Defendants  
24 PFIZER INC., PHARMACIA  
25 CORPORATION, AND G.D. SEARLE  
26 LLC

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